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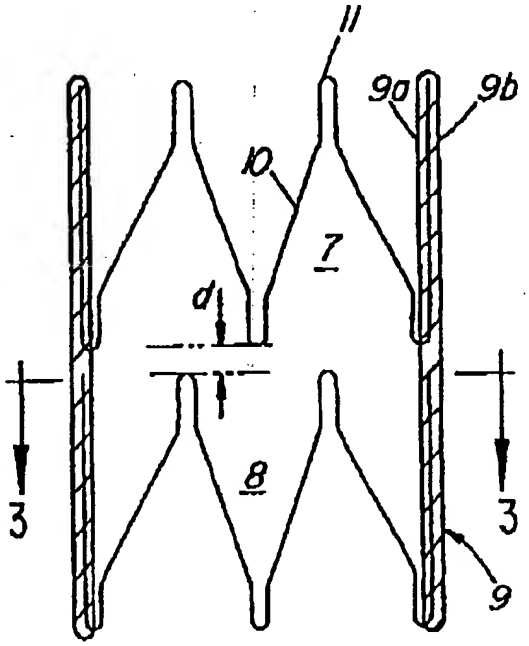
(54) Title: A SELF-EXPANDING ENDOVASCULAR STENT ASSEMBLY, A METHOD FOR THE MANUFACTURE THEREOF AND A STENT INTRODUCER SET COMPRISING SUCH A STENT ASSEMBLY AND AN INTRODUCER CATHETER FOR INTRODUCTION OF SAID STENT INTO A BODY PASSAGE OR DUCT OF A PATIENT

(57) Abstract

A self-expanding endovascular stent assembly comprises at least one stent segment (7, 8) formed by a single piece of wire arranged in a closed zig-zag configuration with struts (10) joining each other joints (11) and a covering sleeve (9). The stent segment (7, 8) is compressible from an expanded condition with a first radius (R) into an introduction condition with second radius (r). The struts (10) are retained solely by the sleeve (9), which is relatively inelastic and has a thickness of not more than 1 % of the first radius (R). A stent introducer set comprising the stent assembly includes an introducer catheter having an internal radius not exceeding 25 % of said first radius.



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A self-expanding endovascular stent assembly, a method for the manufacture thereof and a stent introducer set comprising such a stent assembly and an introducer catheter for introduction of said stent into a body passage or duct of a patient.

The invention relates to a self-expanding endovascular stent assembly comprising at least one stent segment with a metal wire body formed by a single piece of wire arranged in a closed zig-zag configuration including an endless series of struts joining each other in an equal number of joints and a covering sleeve made of a bio-compatible plastic film material, said stent segment being compressible from an expanded condition of a mainly cylindrical shape having a first radius into an introduction condition in which it assumes a smaller second radius.

Endovascular stents of this type is generally used in preventing restenosis or closure by tumors of passageways and ducts in the body of a patient and for percutaneous repair of aneurysms.

From EP-A-0 480 667 a stent assembly of this kind is known in which the metal wire bodies of one or more stent segments are surrounded by a flexible, elastic sleeve, e.g. of nylon, covering the gaps between the struts of the metal wire bodies. The joints between the struts at either end of each segment are shaped into eyes by bending the wire to form a cusp and, then, welding or soldering the wire back upon itself. The stent segments are firmly attached to the flexible sleeve either by stitching or glueing or embedding the segments in the sleeve when the latter is made of a plastic material. The stent segments are connected with each other by tieing the eyes formed at the joints of two segments with thread.

Whereas this prior art device is capable of percutaneous implantation, e.g. in the bilary duct and, due to the covering flexible sleeve, is effective for permanent prevention of in-growth of a tumor between the struts of the segment, it suffers from various practical disadvantages. On one hand, the manufacture is relatively complicated due to the welding or soldering operation required for forming the eyes at the joints of the struts and the mutual connection of stent segments by tieing the eyes of two stent segments positioned end to end with thread. Since proper implantation requires the stent assembly to be able to resist contraction along the axis, application of the sleeve material to the stent segments must take place in the compressed condition of the latter.

Moreover, the thread used for tieing the eyes of two segments together will add to the minimum thickness of the stent in the compressed condition which sets a lower limit to the internal diameter of the catheter used for percutaneous introduction.

From published international patent application WO 9206734 a multistage stent assembly is known which is made up of a number of unit structures that are prevented from separation by means of rod-like connecting members joining the bends of appointed structures together. The assembly is wrapped by a mesh made. e.g. of nylon coated with silicone rubber. Also in this prior art stent the additional connecting members will add to the minimum thickness of the stent assembly in the collapsed condition.

On the background of this prior art it is the object of the invention to provide an improved endovascular stent assembly of the kind defined above offering the advantages of a less complicated manufacture and a further reduced overall diameter in the collapsed

condition used for introduction of the stent, thereby permitting introduction through a relatively narrow catheter as well as an improved flexibility without any tendency to kinking in the collapsed condition so as to permit easy introduction also through curved or narrow passageways or ducts.

According to the invention a self-expanding stent assembly of the kind defined is characterized in that the struts of said metal wire body are retained solely by said sleeve, said sleeve being relatively unelastic and having a thickness of not more than 1 % of said first radius.

By retaining the struts of the metal wire body of each stent segment solely by the relatively inelastic, but still flexible sleeve of a small thickness the connecting threads or rods used in the above-mentioned prior art structures are avoided, so that in addition to the thin sleeve itself the only elements to be elastically deformed in the collapsed condition will be the wire struts. The use of a relatively inelastic sleeve permits application of the sleeve material to the stent segment or segments in their expanded uncompressed condition.

As a result thereof in a multistage embodiment of the stent assembly of the invention several coaxial stent segments will be connected solely through the sleeve and be axially displaces relative to one another to permit axial expansion of each stent segment in the compressed condition.

The invention also relates to a method of manufacturing a self-expanding stent assembly of the kind set forth, which is characterised in that at least one stent segment is made by forming a metal wire body from a single piece of wire arranged in a closed zig-zag configuration with a series of struts and joints to form

a mainly cylindrical shape having said first radius, a plastic film covering being applied to said metal wire body in a thickness not exceeding 1 % of said first radius in such a way as to connect said film material with the wire material of said metal wire body in said joints.

Moreover, the invention also relates to a stent introducer set comprising the self-expanding stent assembly as defined herein before and an introducer cathether for introduction of said stent assembly into a passageway or duct of a patient. According to the invention such an introducer set is characterized in that the introducer catheter has an internal radius not exceeding 25 % of said first radius.

In the following the invention will be further explained with reference to the accompanying schematical drawings, in which

fig. 1 is a partial side representation of a prior art stent assembly as disclosed in EP-A-0 480 667 mentioned above;

fig. 2 is a partial side representation of an embodiment of stent assembly according to the invention in its expanded condition;

fig. 3 is a cross-sectional representation of the stent assembly in fig. 2;

fig. 4 is a side representation of the stent assembly in figs. 2 and 3 in a partly compressed condition; and

figs. 5 and 6 are schematical illustrations of the dimensional features of the stent assembly according to the invention.

Fig. 1 shows two segments 1 and 2 of the prior art stent known from EP-A-0 480667 surrounded by a flexible elastic sleeve 3 which may be of nylon and to which segments 1 and 2 are firmly attached by stitching or

gluing or being embedded in sleeve 3. Each of segments 1 and 2 is formed from a metal wire body formed from a single piece of wire arranged in a closed zig-zag configuration with an endless series of struts 4 joining each other in joints 5 shaped into eyes which are tied with thread 6 to connect segments 1 and 2 with each other.

In fig. 2 two segments 7 and 8 of an embodiment of a stent assembly according to the invention is shown in the expanded state assumed in the position of use of the stent. Segments 7 and 8 are in this embodiment connected solely through the surrounding sleeve 9, i.e. with out tiening the joints 11 between the struts 10 together. The sleeve 9 is made of a relatively inelastic material such as high-density polyethylene and has a small thickness of not more than 1 per cent of the radius R of the stent in the expanded condition as also shown in fig. 3, said thickness being preferably not greater than 30 μ, but preferably at least 20 μ.

As shown in fig 3 sleeve 9 may in order to retain the metal wire bodies of segments 7 and 8 be composed of two layer of film 9a and 9b each having a thickness of e.g. 12 μ.

In fig. 4 the stent assembly of figs. 2 and 3 is shown in its compressed state of introduction in which the radius r is substantially smaller than radius R in the expanded state.

Since for the stent assembly of the invention the sleeve 9 is applied to stent segments 7 and 8 in the expanded state due to the relative inelastic properties of the sleeve material, segments 7 and 8 are arranged in sleeve 9 to be axially displaceable with a mutual separation d in the expanded state which as more clearly apparent from fig. 5 is determined by

$$d = L(1 - \cos \alpha/2),$$

where L is the length of each of struts 10 and 8 and α is the angle included between two successive struts 10 of the metal wire body of each segment 7 or 8. As also shown in fig. 5, x represents the axial length of each segment 7 or 8 in the expanded state, and x + d represents the avial length of each segment 7 or 8 in the compressed state of introduction.

Thereby, compression of the stent into the introduction state shown in fig 4 without segments 7 and 8 conflicting with or overlapping each other is made possible.

Since segments 7 and 8 are not firmly attached to sleeve 9 and are not tied together by an additional thread as in the prior art stent of figs. 1 - 4, the external radius r in the introduction state may be minimized.

Thus, assuming that the metal wire body of each of segments 7 and 8 is made up of 13 struts joining each other in 7 joints and further that the wire thickness of each strut is 0.25 mm, the radius of curvature of each joint is 0.32 mm and the sleeve 9 is composed of two layers of film each with a thickness of 12 μ the area of occupation of the sleeve 9 would for an external radius R = 5 mm in the expanded state amount to

$$A_{sleeve} = 2 \pi (5^2 - 4.988^2) = 0.753 \text{ mm}^2$$

and the area of occupation of the metal wire body in the compressed state would ideally amount to

$$A_{metal} = 2 (0.32 + 0.25) \times 0.25 \times 7 = 1.995 \text{ mm}^2$$

Thereby, the total area of occupation would be

$$A_{\text{wire}} + A_{\text{metal}} = 2.748 \text{ mm}^2$$

and the stent would easily fit into an introducer catheter of a minimum internal radius of 1,25 mm, such as a 7 French catheter having an internal diameter of 2.33 mm and an internal cross sectional area of 4.276 mm^2.

PATENT CLAIMS

1. A self-expanding endovascular stent assembly comprising at least one stent segment (7, 8) with a metal wire body formed by a single piece of wire arranged in a closed zig-zag configuration including an endless series of struts (10) joining each other in an equal number of joints (11) and a covering sleeve (9) made of a bio-compatible plastic film material, said stent segment (7, 8) being compressible from an expanded condition of a mainly cylindrical shape having a first radius (R) into an introduction condition in which it assumes a smaller second radius (r), characterized in that the struts (10) of said metal wire body are retained solely by said sleeve (9), said sleeve being relatively inelastic and having a thickness of not more than 1 % of said first radius (R).

2. A self-expanding stent assembly as claimed in claim 1, characterized by comprising several stent segments (7, 8) which are axially displaceable with a mutual separation and are connected solely through said sleeve (9).

3. A self-expanding stent assembly as claimed in claim 2, characterized in that said mutual separation is greater than $L(1 - \cos \alpha/2)$, where L is the length of each of said stent segments (7, 8) and α is the angle included between two successive struts (10) of said metal wire body.

4. A self-expanding stent assembly as claimed in claim 1, 2 or 3, characterized in that said sleeve (9) is made of high-density polyethylene.

5. A self-expanding stent assembly as claimed in any of the preceding claims, characterized in that said second radius (r) is smaller than 25 % of said first radius (R).

6. A self-expanding stent assembly as claimed in any of the preceding claims, c h a r a c t e r i z e d in that at a value of said first radius(R) of 5 mm the thickness of said sleeve (9) is not greater than 30 μ.

7. A self-expanding stent assembly as claimed in claim 6, c h a r a c t e r i z e d in that the thickness of said sleeve (9) is at least 20 μ.

8. A self-expanding stent assembly as claimed in any of the preceding claims, c h a r a c t e r i z e d in that said joints (11) have a radius of curvature not exceeding 1.3 times the wire thickness.

9. A self-expanding stent assembly as claimed in any of the preceding claims, c h a r a c t e r i z e d in that said metal wire body comprises 7 joints (11).

10. A method of manufacturing a self-expanding stent assembly as claimed in any of the preceding claims, c h a r a c t e r i z e d in that at least one stent segment (7, 8) is made by forming a metal wire body from a single piece of wire arranged in a closed zig-zag configuration with a series of struts (10) and joints (11) to form a mainly cylindrical shape having said first radius (R), a plastic film covering being applied to said metal wire body in a thickness not exceeding 1 % of said first radius (R) in such a way as to connect said film material with the wire material of said metal wire body in said joints (11).

11. A stent introducer set comprising a self-expanding stent assembly as claimed in any of claims 1 to 9 and an introducer catheter for introduction of said stent assembly into a body passage or duct of a patient, c h a r a c t e r i z e d in that said introducer catheter has an internal radius not exceeding 25 % of said first radius (R).

12. A stent introducer set as claimed in claim 11, c h a r a c t e r i z e d in that at a value of said

first radius of 5 mm said introducer is conducted through a catheter has an internal diameter of 7 french (2,33 mm).

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PRIOR ART

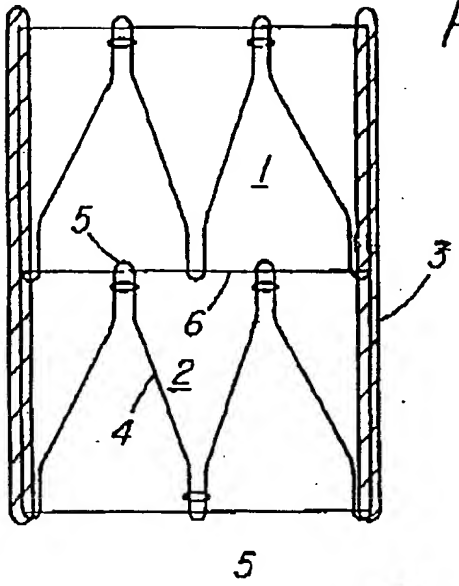

FIG. 1

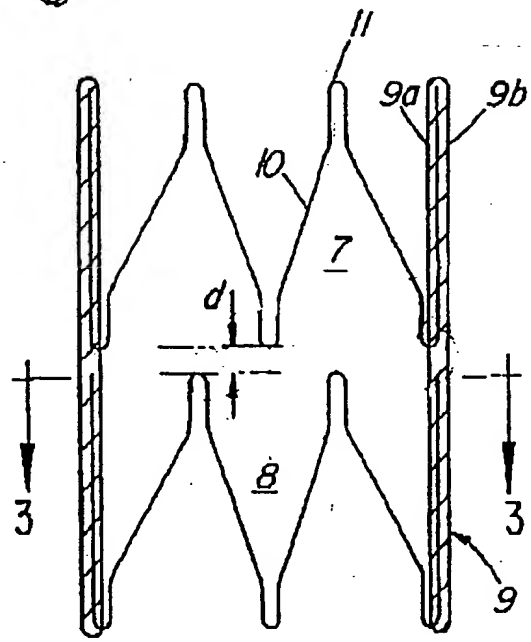

FIG. 2

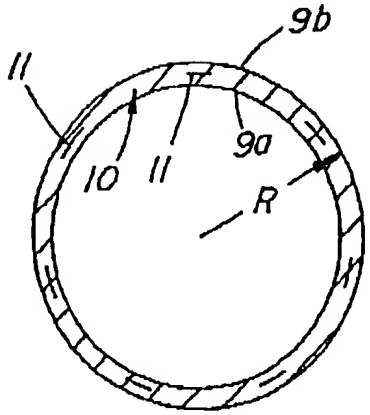

FIG. 3

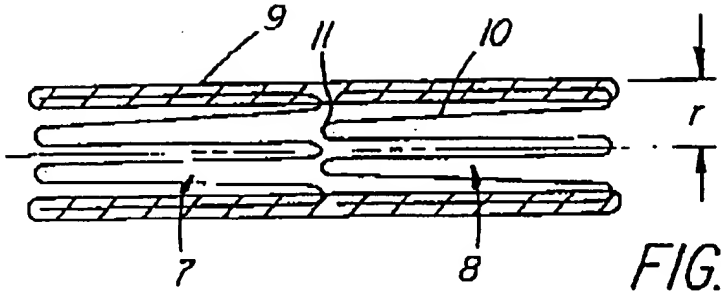

FIG. 4

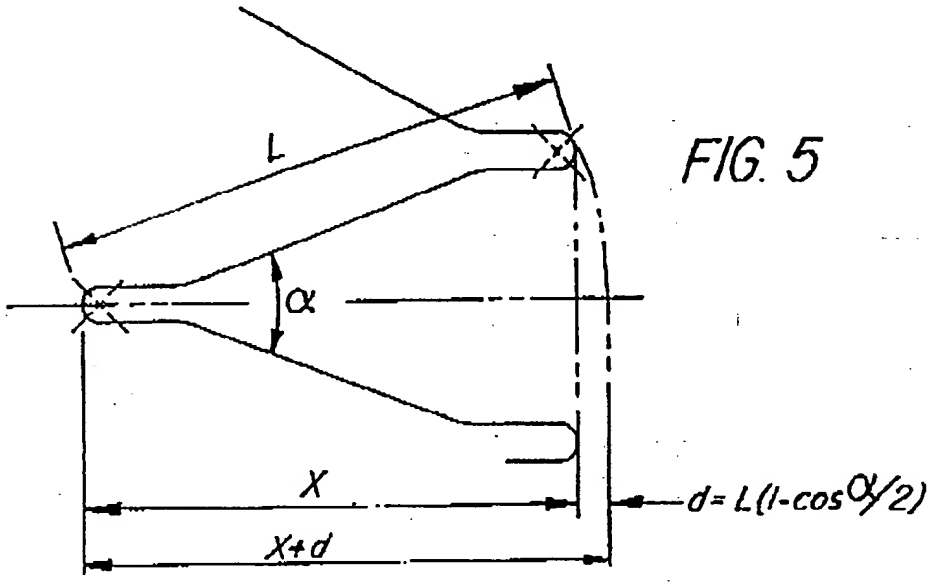

FIG. 5

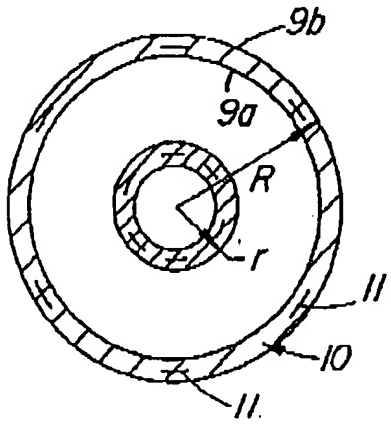

FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 96/00378

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/06
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

QUESTEL 2

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5123917 A (PETER Y. LEE), 23 June 1992 (23.06.92), column 4, line 42 - column 5, line 61, figures 1-5	1-5,10-12
A	US 4604762 A (T.C.ROBINSSON), 12 August 1986 (12.08.86), column 8, line 5 - line 16, figure 12	1-3,10
A	US 5282824 A (C.GIANTURCO), 1 February 1994 (01.02.94), figures 1-6	1-5,10-12
A	US 5403341 A (R.J.SOLAR), 4 April 1995 (04.04.95)	1,10-11

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
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Name and mailing address of the ISA/ Swedish Patent Office, Box 5055, S-102 42 STOCKHOLM, Facsimile No. + 46 8 666 02 86	Authorized officer: Leif Brander, Telephone No. + 46 8 782 25 00

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INTERNATIONAL SEARCH REPORT

Informati on patent family members

28/10/96

Int· ·tional application No.
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A- 5123917	23/06/92	NONE		
US-A- 4604762	12/08/86	CA-A-	1207105	08/07/86
		DE-A-	3204719	16/09/82
		FR-A,B-	2499847	20/08/82
		GB-A,B-	2092894	25/08/82
		JP-A-	57150954	17/09/82
		US-A-	4731073	15/03/88
US-A- 5282824	01/02/94	US-A-	5507771	16/04/96
		AT-T-	135555	15/04/96
		AU-B-	633453	28/01/93
		AU-A-	8568391	11/06/92
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		DE-U-	9117152	11/07/96
		DE-D,T-	69118083	22/08/96
		EP-A,B-	0480667	15/04/92
		SE-T3-	0480667	
		ES-T-	2085435	01/06/96
		JP-A-	4263852	18/09/92
		JP-B-	6093920	24/11/94
US-A- 5403341	04/04/95	US-A-	5549635	27/08/96